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Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket # 97N-484S

To Whom It May Concern:

I have been made aware of a proposed FDA regulation concerning new proposed requirements for the use of allograft material as medical devices.

In the course of our practice of clinical neurosurgery, we have been using various allograft materials for more than 20 years. We have been assured by suppliers, often bone banks, that the materials are FDA approved and that they are safe. To our knowledge, in the use of well over 3,000 such devices we have never had a complication attributable to a defective, contaminated, or otherwise inadequately functioning allograft.

I would urge that you not implement any new regulations that would compromise what are currently a very effective means of providing safe materials for use in patients who need them. Any interruption of the available supply of these materials, or regulations that make them more difficult to obtain, would represent a serious impediment to patient safety and to the successful treatment of serious problems.

Sincerely,

Andrew B. Kaufman, M. D.

ABK/llr

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